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10/533,235	04/29/2005	Masaya Nishio	271564US0PCT	5068
22850	7590	04/01/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER WESTERBERG, NISSA M	
			ART UNIT	PAPER NUMBER
			1618	
			NOTIFICATION DATE	DELIVERY MODE
			04/01/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/533,235	Applicant(s) NISHIO, MASAYA	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5, 8, 10 - 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 8, 10 - 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed January 26, 2009 have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Objections

1. Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claim 1, component (B-1) is defined as an oil ingredient having a volatility of not less than $0.2 \text{ mg/cm}^2\text{hr}$, or in other words, a volatility greater than $0.2 \text{ mg/cm}^2\text{hr}$. Claim 10 requires component (B-1) to be a mixture of two kinds of oil, which is broader than claim 1 in which this component is comprised of one oil ingredient. Additionally, the volatility of this component is required in claim to be not more than $0.1 \text{ mg/cm}^2\text{hr}$, or in other words, a volatility of less than $0.1 \text{ mg/cm}^2\text{hr}$, a range which is not encompassed by the range present in claim 1. Because of the how the component is defined in claim 1, claim 10 is not reciting an additional ingredient that are added to the component (B-1) recited in claims but broadening the constituents of this component and thus claim 10 fails to further limit claim 1.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 has been amended so that component is divided in two components (B-1) and (B-2) which have different volatilities. Claim 8 recites that component (B) is at least one selected from the list provided. Because of the amendments to the claims, it is unclear if this list of possible components applies to component (B-1) or (B-2) or could even possibly be an additional ingredient if the volatilities of some of these compounds falls outside the definitions of components (B-1) and (B-2) now recited in claim 1.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 2, 5, 8, 10, 11, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 07-277923 (Note: a copy of a human translation of this document has been provided with this action to supplement the machine translation previously mailed). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 1, 2008 and those set forth below.

Applicant traverses this rejection that limitations from claims 6 and 9, claims to which this rejection was not applied, have been incorporated into claim 1. Therefore, this rejection no longer applies and should be withdrawn.

These arguments are not found to be persuasive. As indicated on p 2 of the October 1, 2008 Office Action, claims 5 – 9 were improper multiple dependent claims that were not further treated on the merits and therefore the limitations present in those claims were not examined. JP'923 teaches that hard oils such as paraffin and ceresin, pasty oil ingredients such as Vaseline and heavy liquid isoparaffin and liquid oils such as liquid paraffin and squalene can be blended in the compositions of the present invention (§ [0013]). The prepared examples include multiple items from this list.

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It would have been obvious to one of ordinary skill in the art at the time of the instant invention to select various ingredients from those disclosed by JP'923 as suitable for inclusion in the composition and to determine the optimal amounts of each of those ingredients in the composition. As discussed previously, the viscosity of the final composition will be determined by the amounts and viscosity of the various components of the composition. JP'923 discloses the optimal amount of component a is 1.0 – 5.0 weight percent ([¶ 0008]) and the optimal blend amount of the polar oil component ranges from 3.0 – 50.0 weight percent, and the ratios of these two amounts encompasses the range claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. It also would be obvious to one of ordinary skill in the art to apply the composition to the skin of a subject as the person in need of the composition. All human subjects are exposed to body fluids and wastes as these materials are contained within the body. As the active step of the method, applying to the skin of a subject in need thereof is taught by the cited art, the preamble of the claim of protecting the skin must necessarily be met.

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7. Claims 1, 2, 5, 8, 10 – 12, and 15 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP'923 as applied to claims 1, 2, 5, 8, 10, 11, 15, 17 and 18 above further in view of Ziemelis et al. (US 4,472,566). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 1, 2008 and those set forth below.

Applicant traverses this rejection that limitations from claims 6 and 9, claims to which this rejection was not applied, have been incorporated into claim 1. Therefore, this rejection no longer applies and should be withdrawn.

These arguments are not found to be persuasive. As indicated on p 2 of the October 1, 2008 Office Action, claims 5 – 9 were improper multiple dependent claims that were not further treated on the merits and therefore the limitations present in those claims were not examined. As discussed above, JP'923 teaches a composition as disclosed by claim 1 and as discussed in greater detail on p 6 of the rejection mailed on October 1, 2008, Ziemelis teaches that compositions with similar components can be applied by spraying.

8. Claims 1, 2, 5, 8, 10 – 13, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP'923 and Ziemelis et al. as applied to claims 1, 2, 5, 8, 10 – 12, and 15 – 18 above, and further in view of Smith et al. (US 6,001,380). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 1, 2008 and those set forth below.

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Applicant traverses this rejection that limitations from claims 6 and 9, claims to which this rejection was not applied, have been incorporated into claim 1. Therefore, this rejection no longer applies and should be withdrawn.

These arguments are not found to be persuasive for the reasons discussed above.

9. Claims 1, 2, 5, 8, 10, 11, 13 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP'923 as applied to claims 1, 2, 5, 8, 10, 11, 15, 17 and 18 above, and further in view of Tate et al. (US 2003/0130635).

JP'923 discloses cosmetic composition comprising a block polymer with a structural unit of a linear polysiloxane-polyalkoxyalkylene block polymer and multiple oil ingredients.

JP'923 does not disclose the application of such a composition to subject exposed to environmental chemical irritants or allergens that have an adverse effect on the skin of said subject or the application to the skin of the composition in a material, such as a diaper, impregnated with the composition.

Tate et al. discloses a composition with superior spreading and distribution properties that is applied to the body-facing material of disposable absorbent articles such as diapers or wound dressings (§ [0001]). The properties of the compositions are such that they can act as a barrier against urine, feces or other body exudates or irritants (§ [0006]). The composition is applied to the skin surface of the wearer from the absorbent article and reduces irritation of the skin caused by exudates (§ [0012]). These

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compositions comprise emollients such as vegetable, animal or mineral oils and emulsifying silicone elastomers such as organopolysiloxane crosspolymers in which the organo groups can be hydroxyl-terminated polyoxyalkylene polyethers (§ [0022]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to apply the composition of JP'923 with improved adhesiveness and reduced stickiness (§ [0001]) of JP'923) to the skin by way of a diaper impregnated with the composition in order to protect the skin from exudates, body fluids, and irritants. One of ordinary skill in the art would be motivated to apply the composition in this manner as Tate et al. teaches that diapers or other adsorbent articles impregnated with this material are suitable for the application of composition with similar ingredients.

10. Claims 1, 2, 5, 8, 10, 11, 15 and 17 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP'923 as applied to claims 1, 2, 5, 8, 10, 11, 15, 17 and 18 above, and further in view of Okada et al. (US 5,463,009).

JP'923 discloses cosmetic composition comprising a block polymer with structural unit of a linear polysiloxane-polyalkoxyalkylene block polymer and multiple oil ingredients.

JP'923 does not disclose the inclusion of methylpolysiloxane, liquid paraffin and decamethylcyclopentasiloxane in the composition.

Okada et al. discloses that cosmetics silicone derivative polymers may further contain other oil components for common cosmetics including cyclic silicones such as

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decamethylcyclopentasiloxane, nonvolatile silicones such as methylpolysiloxane, liquid paraffin and liquid isoparaffin (col 5, ln 15 – 24).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition according to JP'923 and to include methylpolysiloxane, liquid paraffin and decamethylcyclopentasiloxane in the composition. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Okada et al. discloses that such ingredients are suitable for inclusion in cosmetics containing siloxane polymers and the list overlaps with this list presented in JP'923 as optional ingredients. Selection of a combination the components from a list of known ingredients in the art taught as suitable for inclusion would part of routine optimization that one of ordinary skill in art would routinely practice and would reasonably expect success. The selection would be based on cost and availability of the various ingredients, any interactions that may result in an unsuitable interactions and materials that will give a composition of an appropriate form.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW